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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,959	02/28/2005	Lucas Cyril Gerard Van Der Heyden	4662-2	3062

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,959	VAN DER HEYDEN ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment to the claims (albeit minimal) and response of 04/24/2006, to the attempted first action on the merits over the amorphously claimed subject matter, is acknowledged. For instance, the Examiner is in utter confusion as to the breadth of the now amended claim 15 to: "Method of using a composition comprising a peptide fraction which comprises having a subject ingest the composition". Notwithstanding even the opening grammatical awkwardness of a claim not beginning with "A", the claim reads on a subject taking a drink of milk.

Claims 1-18 remain pending. Applicant has amended the former USE claims 14-18, to now be distinct methods of use (as opposed to their original examination as product claims due to nonstatutory subject matter). Thus, there being no special technical feature that runs through the respective inventions (a myriad of art being found by the US/IA on the combination, and no novel technical feature being present between the distinct groups; see below under Lack of Unity), restriction is necessary (even though the Examiner made a bona fide attempt to search and examine the originally filed claims, in anticipation of an amendment to distinctly claim the invention). Restriction following a first action on the merits is proper in this situation, "as soon as the need for a proper requirement develops", as evidenced by Applicant's amendment to distinctly claim the subject matter of the invention, wherein the breadth is such that an undue search burden remains, see MPEP section 811. (See MPEP 811).

The disposition as to the presently claimed subject matter, stated at the outset of the first action, by this Office as well as the International Authority's office is once again restated:

The present application is 371 of PCT/EP03/09790. The related International Search Report and Written Opinion therefrom covers virtually identical claims as presented here (other than a preliminary amendment to remove multiple dependencies). In Box I.2 of the Search Report it was indicated that "claims 1-18 relate to compositions, uses and methods involving a compound defined by reference to a desirable characteristic or property, namely sensitizing to insulin. [] In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. []A compound cannot be sufficiently defined by its mechanism of action and/or its pharmacologic profile." The International Authorities struggle with the search of the invention based on the claim language/application as filed, is evidenced by the 17 references cited therein, each reading all or in part over the claims. and search thereof.

Notwithstanding the difficulty in searching structure-based subject matter, which is at the core of the present invention, which has been claimed by language to said structures mechanism of action and/or pharmacologic profile; a reasonable and diligent attempt has been made to search/examine the invention as claimed; similar to the problem faced by the International Searching/Examining Authority. Claims 1-18 are herein examined on the merits.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-13, drawn to a composition comprising ANY insulin sensitizer and ANY peptide fraction (MISNOMER since claim 3, under a reasonable interpretation contemplates a single amino acid as quote the "peptide fraction". A single amino acid is not a peptide).

II. Claim 14, drawn to a method of ingesting a composition comprising ANY insulin sensitizer and ANY peptide fraction.

III. Claims 15-16, drawn to a method of ingesting a composition comprising a peptide fraction.

IV. Claim 17-18, drawn to a method of treating/retarding diabetes comprising drinking a composition comprising ANY insulin sensitizer and ANY peptide fraction.

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

Markush Group-Lack of Unity

I. The inventions are independently drawn to a combination of insulin sensitizers (e.g. niacin, chromium) and a peptide or amino acid "fraction". For the members of a Markush group to have unity of invention, *all* members must have a common core structure or be a member of an art recognized class. Neither a common core structure or an art recognized class, applies to either component of the combination, namley the insulin sensitizers or to amino acids or peptide 'fractions'. The distinct amino acids and peptides lacking a common core structure, even alone, which must be present, are in particular not "an art recognized class". (Furthermore, even if an argument could be made for a markush group in either component, there that a no substantial (novel) core structure therebetween; thus there exists no "novel" technical feature which rises to the level of creating a 'special' technical feature that runs through the invention (see cited art in first action)). Thus, the Markush groups, and hence Inventions drawn thereto, lack unity of invention. (See Annex B to PCT Administrative Instructions, P. A1-59).

Election of a Single Composition as the Invention

The inventions of Groups I-IV are drawn to or the use of a composition comprising ANY insulin sensitizer and ANY amino acid and/or peptide fraction or simply ANY amino acid and/or peptide fraction (Group III). The search of any combination or distinct amino acid and/or peptide fraction, is a separate and distinct search which is not coextensive. Therefore, irrespective of which Group (Groups I-IV) is elected as the invention, Applicant must elect a SINGLE insulin sensitizer (e.g. niacin) and/or a SINGLE amino acid and/or peptide fraction peptide (e.g. leucine), to which the elected invention will be examined as drawn to. Should

Applicant have any questions prior to election, Applicant is advised to the call to the Examiner by the contact information below. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 06/09/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654